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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WENDEROTH, LIND & PONACK, L.L.P.

Suite 800

2033 K Street, N.W.

Washington, DC 20006

EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 10/02/2002

MP

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/725,752

Applicant(s)

TOKUNAGA ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 4-5, 10, and 14, drawn to reagents "having a specific affinity for" nucleic acids and diagnostic methods in which nucleic acids are detected, classified in class 435, subclass 6 and class 536, subclass 24.31.
 - II. Claims 1-2, 4-5, 10, and 14, drawn to reagents "having a specific affinity for" nucleic acids and diagnostic methods in which nucleic acids are detected, classified in class 435, subclass 6 and class 536, subclass 24.31.
 - III. Claims 1, 3-5, 10-11, and 14, drawn to reagents "having a specific affinity for" nucleic acids and diagnostic methods in which nucleic acids are detected, classified in class 435, subclass 6 and class 536, subclass 24.31.
 - IV. Claims 6, 9, 12, and 15, drawn to reagents "having a specific affinity for" proteins and diagnostic methods in which proteins are detected, classified in class 435, subclass 7.1 and class 530, subclass 387.1.
 - V. Claims 6-7, 9, 12, and 15, drawn to reagents "having a specific affinity for" proteins and diagnostic methods in which proteins are detected, classified in class 435, subclass 7.1 and class 530, subclass 387.1.
 - VI. Claims 6, 8-9, 12-13, and 15, drawn to reagents "having a specific affinity for" proteins and diagnostic methods in which proteins are detected, classified in class 435, subclass 7.1 and class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I and IV, I and V, I and VI, II and IV, II and V, II and VI, III and IV, III and V, and III and VI are drawn to patentably distinct methods and patentably distinct combinations of reagents. The reagents of Group I include nucleic acids, which are composed of nucleotides, while the reagents of Group II include antibodies, which are composed of amino acids. The reagents of Group I function in, e.g., methods of nucleic acid hybridization, while the reagents of Group II function in, e.g., methods of protein detection and purification. Accordingly, the reagents of the two Groups have different structures and different functions. The methods of Group I require, e.g., the use of nucleic acid probes in the detection of genes, while the methods of Group II require, e.g., the use of antibodies in the detection of proteins. Accordingly, the methods of the employ patentably distinct products in different process steps. Thus, the methods and reagents of Group I are patentably distinct from those of Group II.

Election Requirement Applicable to Groups I, III, IV and VI

3. It is noted that Groups I-III have the same classification as one another, as do Groups IV-VI. However, Groups I-III and Groups IV-VI encompass numerous patentably distinct combinations of reagents and methods employing such combinations. Specifically:

Group I encompasses 14 possible combinations of the 4 reagents set forth in claim 1, and the 4 genes detected by those reagents as set forth in claim 10. It is noted that Group I excludes the combination of all 4 reagents/all 4 genes; this constitutes Group II (see below).

Group II includes dependent claim 2, which requires all 4 reagents of claim 1.

Group II is drawn to the combination of all 4 reagents of claim 1/all 4 genes of claim 10.

Group III encompasses 45 possible combinations of reagents/genes, as set forth in dependent claims 3 and 11. Specifically the Group encompasses all possible combinations of the 4 reagents of claim 1/ 4 genes of claim 10, in combination with a cytochrome oxidase subunit I reagent/gene (15 combinations), in combination with a cytochrome b reagent/gene (15 combinations), and in combination with both a cytochrome oxidase subunit I reagent/gene and a cytochrome b reagent/gene (15 combinations), for a total of 45 possible combinations.

Group IV encompasses 14 possible combinations of the 4 reagents set forth in claim 6, and the 4 proteins detected by those reagents as set forth in claim 12. It is noted that Group IV excludes the combination of all 4 reagents/all 4 proteins; this constitutes Group V (see below).

Group V includes dependent claim 7, which requires all 4 reagents of claim 6. Group V is drawn to the combination of all 4 reagents of claim 6/all 4 proteins of claim 12.

Group VI encompasses 45 possible combinations of reagents/proteins, as set forth in dependent claims 8 and 13. Specifically the Group encompasses all possible combinations of the 4 reagents of claim 6/ 4 proteins of claim 12, in combination with a cytochrome oxidase subunit I reagent/protein (15 combinations), in combination with a cytochrome b reagent/protein (15 combinations), and in combination with both a

cytochrome oxidase subunit I reagent/protein and a cytochrome b reagent/protein (15 combinations), for a total of 45 possible combinations.

Thus, Groups I-III and Groups IV-VI encompass numerous patentably distinct combinations of reagents and methods employing such combinations. Each reagent combination has a different structure and different functional properties. Similarly, each method requiring detection of a different combination of genes/proteins necessitates detection of a set of molecules that has a combination of structures and functions different from every other set of molecules. A different field of search would be required to identify art pertinent to each combination, and a different set of references would be applicable to each combination. Accordingly, a search of more than one patentably distinct combination of reagents of Groups I-III or Groups IV-VI would pose a serious burden on the examiner. Therefore, a further restriction requirement is applied to Groups I, III, IV, and VI. If applicant elects either of Groups I or III, applicant is further required to elect a single combination of reagents/genes. If applicant elects either of Groups IV or VI, applicant is further required to elect a single combination of reagents/proteins. **This is not an election of species. Applicant is advised that examination will be restricted to only the elected combination.**

It is noted that as Groups II and V each encompass only a single combination of reagents, no further election is required if either of these Groups is elected. It is further noted that those claims included in multiple Groups (claims 1, 4-6, 9-10, 12, and 14-15) will be examined only to the extent that they read upon the elected Group/combination of molecules.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and/or because Inventions I-VI require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
September 29, 2002



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600